

37 CFR 1.501  
 INFORMATION DISCLOSURE STATEMENT  
 IN A PATENT  
 (use several sheets if necessary)

Docket No.  
 P97,1036

Serial No.  
 09/025,363

Applicant  
 Mark et al.

Filing Date  
 February 18, 1998

Group Art Unit  
 1801/618

## U.S. PATENT DOCUMENTS

Examiner's Initials		Document Number	Date	Name	Class	Subclass	Filing Date If appropriate
7	AA	4,358,465	11/09/82	Brule et al.			
7	AB	4,361,587	11/30/82	Brule et al.			
7	AC	4,427,658	01/24/84	Maubois et al.			
7	AD	4,495,176	01/22/85	Brule et al.			
7	AE	4,670,268	06/02/87	Mahmoud			
7	AF	4,740,462	04/26/88	Brule et al.			
7	AG	4,753,963	06/28/88	Jandacek et al.			
7	AH	4,816,398	03/28/89	Brule et al.			
7	AI	4,920,098	04/24/90	Cotter et al.			
7	AJ	4,931,300	06/05/90	Monte			
7	AK	4,980,450	12/25/90	Brule et al.			
7	AL	5,028,589	07/02/91	Brule et al.			
7	AM	5,053,387	10/01/91	Alexander			
7	AN	5,055,446	10/08/91	Alexander et al.			
7	AO	5,156,875	10/20/92	Monte			
7	AP	5,166,189	11/24/92	Trimbo et al.			
7	AQ	5,221,668	06/22/93	Henningfield et al.			
7	AR	5,223,285	06/29/93	DeMichele et al.			
7	AS	5,260,279	11/09/93	Greenberg			
7	AT	5,422,127	06/06/95	Dube et al.			
7	AU	5,438,042	08/01/95	Schmidl et al.			
7	AV	5,661,123	08/26/97	Stalker et al.			
7	AW	5,714,472	02/03/98	Gray et al.			
7	AX	5,723,446	03/03/98	Gray et al.			

## FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
7	AY	0 189 160	07/30/86	Europe				
	AZ							

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Group Art Unit  
 1801 1419

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

7	BA	Clintec Nutrition Company, <i>Proper Nutrition For ICU Patients Is Critical</i> , Brochure, 1994.
7	BB	Clintec Nutrition Company, <i>When You Create Such A Unique Enteral Formula, It's Hard Not To Create Attention</i> , Brochure, 1994.
7	BC	Clintec Nutrition Company, <i>Crucial Needs Require A Curcial™ Solution</i> , Brochure, 1994.
7	BD	Clintec Nutrition Company, <i>Crucial™ Compared To Perative®</i> , Brochure, 1995.
	BE	Clintec Nutrition Company, <i>When Your First Choice Has To Be Your Best Choice</i> , Reabilan® Brochure (Undated).
	BF	Clintec Nutrition Company, <i>Reabilan HN</i> , Brochure (Undated).
7	BG	Ross Laboratories Brochure, <i>Specialized Elemental Nutrition With Glutamine</i> , The Role of ALITRAQ™ Specialized Elemental Nutrition With Glutamine, 1991.
7	BH	Ross Laboratories Brochure, <i>Introducing ALITRAQ™ Specialized Elemental Nutrition With Glutamine</i> , 1992.
7	BI	Ross Laboratories Brochure, <i>Introducing PERATIVE™</i> , 1992.
7	BJ	Sandoz Nutrition Brochure, <i>IMPACT®</i> , 1993.
7	BK	Sandoz Nutrition Brochure, <i>INTRODUCING IMPACT®</i> , 1989.
7	BL	Sandoz Nutrition Brochure, <i>IMPACT®</i> , 1991.
	BM	Mead Johnson, <i>Enteral Nutritionals Product Handbook</i> , bearing Nos. A2688-2693.
	BN	Mead Johnson <i>Enteral Nutritionals Brochure</i> bearing Nos. B00083.
	BO	Mead Johnson Brochure bearing Nos. B00322-B00323.
7	BP	Mead Johnson, <i>Metabolic and Nutrition Support for Trauma and Burn Patients A Symposium</i> , Abstracts, 1982, pp. 1-13.
7	BQ	<i>Nutritional Care of Metabolically Stressed Patients</i> , Proceedings from the Metabolic and Nutrition Support for Trauma and Burn Patients Symposium, White Sulphur Springs, West Virginia, 1983, pp. 1-77.
7	BR	<i>Principles of Nutritional Support: Proceedings From the Metabolic and Nutrition Support for Trauma and Burn Patients Symposium</i> , White Sulphur Springs, West Virginia, 1982, pp. 1-25.
7	BS	<i>Symposium Highlights Metabolic and Nutrition Support for Trauma and Burn Patients</i> , White Sulphur Springs, West Virginia, 1982, pp. 1-26.
7	BT	<i>TraumaCal, Feeding the Hypermetabolic Patient, Clinical Experience, A Symposium</i> , 1983, pp. 1-74.
	BU	<i>TraumaCal Product Cards</i> bearing Nos. B000001-10.
	BV	<i>TraumaCal Documents</i> bearing Nos. B00088-105.

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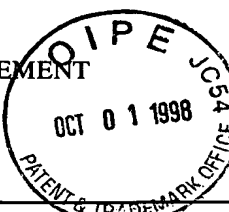
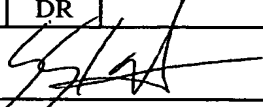
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

7	CA	TraumaCal Document bearing No. B00181. 1983
	CB	TraumaCal Document bearing Nos. B00261-265.
7	CC	TraumaCal Document bearing No. B00293. 1982
7	CD	TraumaCal Document bearing Nos. B00384-385. 1982
	CE	TraumaCal Label bearing No. B00441.
7	CF	TraumaCal Brochure bearing Nos. B00567-570. 1988
7	CG	National Research Council, "Recommended Dietary Allowances, 10th Edition," Washington, D.C.: National Academy Press 1989.
7	CH	Joint FAO/WHO Ad Hoc Expert Committee, "Protein and Energy Requirements: a joint FAO/WHO Memorandum," <i>Bulletin of the World Health Organization</i> , Vol. 57, 1979, pp. 65-79.
7	CI	Bell et al., "Alternative lipid sources for enteral and parenteral nutrition: Long- and medium-chain triglycerides, structured triglycerides, and fish oils", <i>Journal of the American Dietetic Association</i> , Vol. 91, No. 1, 1991, pp. 74-78.
7	CJ	Bjerve et al., "Alpha-linolenic acid deficiency in man: effect of ethyl linolenate on plasma and erythrocyte fatty acid composition and biosynthesis of prostanoids", <i>Am J Clin Nutr</i> , Vol. 46, 1987, pp. 570-576.
7	CK	Borum, "Role of Carnitine in Lipid Metabolism", <i>Lipids in Modern Nutrition</i> , New York: Raven Press, 1987, pp. 51-58.
7	CL	Borum et al., "Carnitine content of liquid formulas and special diets", <i>Am J Clin Nutr</i> , Vol. 32, 1979, pp. 2272-2276.
7	CM	Chernoff et al., "The effect of a very high-protein liquid formula (Replete®) on decubitus ulcer healing in long-term tube-fed institutionalized patients", <i>J Am Diet Assoc.</i> , Vol. 90, 1991.
7	CN	Geggel et al., "Nutritional Requirement for Taurine in Patients Receiving Long-Term Parenteral Nutrition", <i>The New England Journal of Medicine</i> , Vol. 312, No. 3, 1985, pp. 142-146.
7	CO	Greenberger et al., "Medium-Chain Triglycerides: Physiologic Considerations and Clinical Implications", <i>The New England Journal of Medicine</i> , Vol. 280, No. 19, 1969, pp. 1045-1058.
7	CP	Hayes, "Vitamin-Like Molecules (D) Taurine", <i>Modern Nutrition in Health and Disease</i> , 7th Edition, Philadelphia: Lea and Febiger, 1988, pp. 464-470.
7	CQ	Heymsfield et al., "Respiratory, cardiovascular, and metabolic effects of enteral hyperalimentation: influence of formula dose and composition", <i>The American Journal of Clinical Nutrition</i> , Vol. 40, 1984, pp. 116-130.
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Applicant Mark et al.			Filing Date February 18, 1998	Group Art Unit 1801 1614
<b>OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)</b>				
J	DA	Holman, "Function and Biologic Activities of Essential Fatty Acids in Man", <i>Fat Emulsion in Parenteral Nutrition</i> , Chicago: American Medical Association, 1976, pp. 5-14.		
J	DB	Holt, "Medium Chain Triglycerides: A Useful Adjunct in Nutritional Therapy", <i>Gastroenterology</i> , Vol. 53, No. 6, 1967, pp. 961-966.		
J	DC	Kaunitz, "Clinical uses of medium-chain triglycerides", <i>Drug Therapy</i> , Vol. 8, 1978, pp. 91-96.		
J	DD	Law et al., "The Effect of Dietary Protein Depletion on Immunocompetence: The Importance of Nutritional Repletion Prior to Immunologic Induction", <i>Ann. Surg.</i> , Vol. 179, No. 2, 1974, pp. 168-173.		
J	DE	Mahan et al., "The Assessment of Nutritional Status", <i>Krause's Food and Nutrition &amp; Diet Therapy, 8th Edition</i> , Philadelphia: W.B. Saunders Company, 1992, pp. 293-313.		
J	DF	Mascioli et al., "Intravenous Infusion of a Physical Mixture of Medium and Long Chain Triglyceride Emulsion", <i>Clin. Res.</i> , Vol. 33, 1985, 275A.		
J	DG	Nichols et al., "Magnesium supplementation in protein-calorie malnutrition", <i>The American Journal of Clinical Nutrition</i> , Vol. 31, 1978, pp. 176-188.		
J	DH	Randall et al., "Randomized Clinical Trial in Hospitalized Patients Using Intravenous Medium Chain Triglyceride Emulsions", <i>Clin. Res.</i> , Vol. 33, 1985, 276A.		
J	DI	Sailer et al., "Medium Chain Triglycerides in Parenteral Nutrition" <i>Journal of Parenteral and Enteral Nutrition</i> , Vol. 5, No. 2, 1981, pp. 115-119.		
J	DJ	Simopoulos, "Omega-3 fatty acids in health and disease and in growth and development", <i>Am J Clin Nutr</i> , Vol. 54, 1991, pp. 438-63.		
J	DK	Sturman et al., "The Biology of Taurine in Nutrition and Development", <i>Adv. Nutr Res</i> , Vol. 3, 1980, pp. 231-299.		
J	DL	Sucher, "Medium Chain Triglycerides: A Review of Their Enteral Use in Clinical Nutrition", <i>Nutrition in Clinical Practice</i> , 1986, pp. 146-150.		
J	DM	Twyman et al., "High Protein Enteral Feedings: A Means of Achieving Positive Nitrogen Balance in Head Injured Patients", <i>Journal of Parenteral and Enteral Nutrition</i> , Vol. 9, No. 6, 1985, pp. 679-684.		
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Examiner 		Date Considered 4/12/99		
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37 CFR 1.501 INFORMATION DISCLOSURE STATEMENT IN A PATENT (use several sheets if necessary)		Docket No. P97,1036	Serial No. 09/025,363
		Applicant Mark et al.	
		Filing Date February 18, 1998	Group Art Unit 1801 4666/669
OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)			
3	AA	Alexander et al., "Beneficial Effects of Aggressive Protein Feeding in Severely Burned Children", <i>Ann. Surg.</i> , Vol. 192, No. 4, 1980, pp. 505-517.	
7	AB	Anderson et al., "Intestinal Protein Loss During Enteral Alimentation in Critically Ill Patients", <i>J Parenter Enteral Nutr.</i> , Vol. 14 (Suppl), No. 1, 1990, pg. 24, Abstract.	
7	AC	August et al., "Determination of Zinc and Copper Absorption at Three Dietary Zn-Cu Ratios by Using Stable Isotope Methods in Young Adult and Elderly Subjects", <i>Am J Clin Nutr.</i> , Vol. 50, 1989, pp. 1457-1463.	
7	AD	Austin, "Water: Guidelines for Nutritional Support", <i>Nutritional Support Services</i> , Vol. 6, No. 9, 1986, pp. 27-29.	
3	AE	Belcher et al., "Determinants of Urinary Nitrogen Excretion in Burned Patients", <i>Burns</i> , Vol. 14, No. 4, 1988, pp. 303-307.	
7	AF	Bjerve et al., "Alpha-Linolenic Acid Deficiency in Patients on Long-Term Gastric-Tube Feeding: Estimation of Linolenic Acid and Long-Chain Unsaturated n-3 Fatty Acid Requirement in Man", <i>Am J Clin Nutr.</i> , Vol. 5, 1987, pp. 66-77.	
7	AG	Bogden et al., "Zinc and Immunocompetence in Elderly People: Effects of Zinc Supplementation for 3 Months", <i>Am J Clin Nutr.</i> , Vol. 48, 1988, pp. 655-663.	
7	AH	Bogden et al., "Zinc and Immunocompetence in the Elderly: Baseline Data on Zinc Nutriture and Immunity in Unsupplemented Subjects", <i>Am J Clin Nutr.</i> , Vol. 46, 1987, pp. 101-109.	
7	AI	Breslow, "Nutritional Status and Dietary Intake of Patients With Pressure Ulcers: Review of Research Literature 1943 to 1989", <i>Decubitus</i> , Vol. 4, No. 1, 1991, pp. 16-21.	
7	AJ	Brinson, "The Effect of Peptide-Based Diets on the Intestinal Microcirculation in a Rat Model", <i>Nutr Clin Prac.</i> , Vol. 5, 1990, pp. 238-240.	
7	AK	Brinson et al., "Diarrhea Associated With Severe Hypoalbuminemia: A Comparison of a Peptide-Based Chemically Defined Diet and Standard Enteral Alimentation", <i>Critical Care Medicine</i> , Vol. 16, No. 2, 1988, pp. 130-136.	
7	AL	Brinson et al., "Intestinal Absorption of Peptide Enteral Formulas in Hypoproteinemic (Volume Expanded) Rats: A Paired Analysis", <i>Critical Care Medicine</i> , Vol. 17, No. 7, 1989, pp. 657-660.	
7	AM	Bynoe et al., "Nutrition Support in Trauma Patients", <i>Nutr Clin Prac.</i> , Vol. 4, 1988, pp. 137-144.	
7	AN	Cerra et al., "Enteral Nutrition in Hypermetabolic Surgical Patients", <i>Critical Care Medicine</i> , Vol. 17, No. 7, 1989, pp. 619-622.	
7	AO	Cerra et al., "The Effect of Stress Level, Amino Acid Formula, and Nitrogen Dose on Nitrogen Retention in Traumatic and Septic Stress", <i>Ann. Surg.</i> , Vol. 205, No. 3, 1987, pp. 282-287.	
7	AP	Cerra et al., "What's New in Nutrition Support in Critical Care", <i>Perspective in Clinical Nutrition</i> , Kinney, Borum (Eds.), Urban & Schwarzenberg: Baltimore-Munich, 1989, pp. 323-338.	
Examiner		Date Considered	
SSA		4/12/99	
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OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

7	BA	Chandra, "Trace Element Regulation of Immunity and Infection", <i>Journal of the American College of Nutrition</i> , Vol. 4, No. 1, 1985, pp. 5-16.
7	BB	D'Atellis et al., "Branched-Chain Amino Acids", <i>Nutrition in Critical Care</i> , In Zaloga (ed.), St. Louis, MO: Mosby, 1994, pp. 81-106.
7	BC	Dominioni et al., "Enteral Feeding in Burn Hypermetabolism: Nutritional and Metabolic Effects of Different Levels of Calorie and Protein Intake", <i>Journal of Parenteral and Enteral Nutrition</i> , Vol. 9, No. 3, 1985, pp. 269-279.
7	BD	Dominioni et al., "Prevention of Severe Postburn Hypermetabolism and Catabolism by Immediate Intragastric Feeding", <i>J. Burn Care Rehab.</i> , Vol. 5, No. 2, 1984, pp. 106-112.
7	BE	Ehrlich et al., "Effects of Cortisone and Vitamin A on Wound Healing", <i>Annals of Surgery</i> , Vol. 167, No. 3, 1968, pp. 324-328.
7	BF	Ehrlich et al., "Effects of Vitamin A and Glucocorticoids upon Inflammation and Collagen Synthesis", <i>Ann. Surg.</i> , Vol. 177, No. 2, 1973, pp. 222-227.
7	BG	Ehrlich et al., "Effects of Beta-Carotene, Vitamin A, and Glucocorticoids on Collagen Synthesis in Wounds", <i>Proc. Soc. Exp Biol Med.</i> , Vol. 137, No. 1, 1971, pp. 936-938.
7	BH	Fabiani et al., "Oral Hyperalimentation in the Nutritional Management of Burned Patients", <i>SAMJ</i> , Vol. 67, 1985, pp. 768-770.
7	BI	Freeman et al., "Effects of Magnesium Infusions on Magnesium and Nitrogen Balance During Parenteral Nutrition", <i>The Canadian Journal of Surgery</i> , Vol. 25, No. 5, 1982, pp. 570-574.
7	BJ	Goodson et al., "Wound Healing", <i>Nutrition and Metabolism in Patient Care</i> , In: Kinney et al. (Eds.), Philadelphia, PA: WB Saunders, 1988, 635-642.
7	BK	Gottschlich et al., "Enteral Nutrition in Patients with Burns or Trauma", <i>Clinical Nutrition Enteral and Tube Feeding 2nd Edition</i> , In: Rombeau et al. (Eds.), Philadelphia, PA: WB Saunders, 1990, pp. 306-324.
7	BL	Gottschlich et al., "Vitamin Supplementation in the Patient with Burns", <i>J. Burn Care Rehab.</i> , Vol. 11, No. 3, 1990, pp. 275-279.
7	BM	Granger et al., "Intestinal Absorption of Elemental and Standard Enteral Formulas in Hypoproteinemic (Volume Expanded) Rats", <i>Journal of Parenteral and Enteral Nutrition</i> , Vol. 12, No. 3, 1988, pp. 278-281.
7	BN	Hadley et al., "Nutrition and Wound Healing", <i>Top Clin. Nutr.</i> , Vol. 5, No. 4, 1990, pp. 72-81.
7	BO	Hallbook et al, "Serum-Zinc and Healing of Venous Leg Ulcers", <i>Lancet</i> , 1972, pp. 780-782.
7	BP	Hunt, "Control of Wound Healing With Cortisone and Vitamin A", <i>The Ultrastructure of Collagen</i> , In: Longacre JJ (ed.), Springfield, IL: Charles C. Thomas, 1976, pp. 497-508.
7	BQ	Hunt et al., "Effect of Vitamin A on Reversing the Inhibitory Effect of Cortisone on Healing of Open Wounds in Animals and Man", <i>Annals of Surgery</i> , Vol. 170, No. 4, 1969, pp. 633-641.
7	BR	Hunt et al., "Selenium Depletion in Burn Patients", <i>Journal of Parenteral and Enteral Nutrition</i> , Vol. 8, No. 6, 1984, pp. 695-699.

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**OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)**

✓	CA	Ireton-Jones et al., "Nutrition for Adult Burn Patients: A Review", <i>Nutr. Clin. Prac.</i> , Vol. 6, No. 1, 1991, pp. 3-7.
✓	CB	Jahoor et al., "Dynamics of the Protein Metabolic Response to Burn Injury", <i>Metabolism</i> , Vol. 37, No. 4, 1988, pp. 330-337.
✓	CC	Johnson et al., "Metabolism of Medium-Chain Triglyceride Lipid Emulsion", <i>Nutrition International</i> , Vol. 2, No. 3, 1986, pp. 150-158.
✓	CD	Kissileff et al., "Physiology of the Control of Food Intake", <i>Ann. Rev. Nutr.</i> , Vol. 2, 1982, pp. 371-418.
✓	CE	Kubo et al., "Fluid and Electrolyte Problems of Tube-Fed Patients", <i>American Journal of Nursing</i> , Vol. 76, No. 6, 1976, pp. 912-916.
✓	CF	Levenson, "Micronutrients (Vitamins, Trace Minerals)", In ASPEN Program Manual of Proceedings of The 16th Clinical Congress, 1992, pp. 189-198.
✓	CG	Long et al., "Metabolic Response to Injury and Illness: Estimation of Energy and Protein Needs from Indirect Calorimetry and Nitrogen Balance", <i>Journal of Parenteral and Enteral Nutrition</i> , Vol. 3, No. 6, 1979, pp. 452-456.
✓	CH	Mandt et al., "Nutritional Requirements", <i>Nutrition Support Handbook</i> , In: Teasley-Strausberg (ed.), Cincinnati, OH: Harvey Whitney Books Co., 1992, pp. 19-36.
✓	CI	McClave et al., "Immunonutrition and Enteral Hyperalimentation of Critically Ill Patients", <i>Digestive Diseases and Sciences</i> , Vol. 37, No. 8, 1992, pp. 1153-1161.
✓	CJ	Meredith et al., "Visceral Protein Levels in Trauma Patients Are Greater with Peptide Diet Than with Intact Protein Diet", <i>The Journal of Trauma</i> , Vol. 30, No. 7, 1990, pp. 825-829.
✓	CK	Ortiz et al., "A Comparative Post-Operative Study - An Enteral Solution Based on Free Amino Acids", <i>Gastroenterologic Clinique et Biologique</i> , Vol. 9, No. 2, 1985, pp. 182-183.
✓	CL	Pearson et al., "An Estimation of the Potassium Requirements For Equilibrium in Burned Patients", <i>Surgery Gynecology &amp; Obstetrics</i> , Vol. 112, No. 3, 1961, pp. 263-273.
✓	CM	Pories et al., "Acceleration of Wound Healing in Man With Zinc Sulphate Given By Mouth", <i>Lancet</i> , 1967, pp. 121-124.
✓	CN	Prasad et al., "Serum Thymulin in Human Zinc Deficiency", <i>J. Clin. Invest.</i> , Vol. 82, 1988, pp. 1202-1210.
✓	CO	Ringsdorf et al., "Vitamin C and Human Wound Healing", <i>Oral Surgery</i> , Vol. 53, No. 3, 1982, pp. 231-236.
✓	CP	Ross et al., "Wound Healing and Collagen Formation - II. Fine Structure in Experimental Scurvy", <i>The Journal of Cell Biology</i> , Vol. 12, 1962, pp. 533-551.
✓	CQ	Ross et al., "Wound Healing and Collagen Formation - V. Quantitative Electron Microscope Radioautographic Observations of Proline-H <sup>3</sup> Utilization by Fibroblasts", <i>The Journal of Cell Biology</i> , Vol. 27, 1965, pp. 83-106.
✓	CR	Ross et al., "Vitamin A as a Hormone: Recent Advances in Understanding the Actions of Retinol, Retinoic Acid, and Beta Carotene", <i>Journal of The American Dietetic Association</i> , Vol. 93, No. 11, 1993, pp. 1285-1290.

Examiner S. S. S. S.	Date Considered 4/1/99
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7	DA	Sandstead et al., "Zinc and Wound Healing: Effects of Zinc Deficiency and Zinc Supplementation", <i>The American Journal of Clinical Nutrition</i> , Vol. 23, No. 5, 1970, pp. 514-519.
7	DB	Silk, "Nutritional Support in Hospital Practice", Oxford, Blackwell Scientific Publications, 1983, pp. 79-82.
7	DC	Spiller et al., "Malabsorption", <i>Nutrition and Metabolism in Patient Care</i> , Kinney et al. (Eds.), Philadelphia, PA: WB Saunders, 1988, pp. 281-304.
7	DD	Stotts et al., "Nutrition: A Critical Component of Wound Healing", <i>AACN Clin Issues</i> , Vol. 1, No. 3, 1990, pp. 585-594.
7	DE	Szebeni et al., "Vitamin A Levels in the Serum of Burned Patients", <i>Burns</i> , Vol. 7, No. 5, 1981, pp. 313-318.
7	DF	Waxman et al., "Protein Loss Across Burn Wounds", <i>The Journal of Trauma</i> , Vol. 27, No. 2, 1987, pp. 136-140.
7	DG	Ziegler et al., "Efficiency of Enteral Nitrogen Support in Surgical Patients: Small Peptides v Non-Degraded Proteins", <i>Gut</i> , Vol. 31, 1990, pp. 1277-1283.
	DH	
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